

REMARKS

Claims 13, 15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-94, 96-98, 100-112, and 116-123, and 125-130 are pending and under consideration. Applicants respectfully request reconsideration in view of the foregoing amendments and the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action

1. Withdrawn Objections and/or Rejections

Applicants note with appreciation that the rejection of claims 13, 15-21, 23, 28-33, 39, 45, 46, 50, 53, 54, 57-60, 76-78, 85, 87-94, 96-98, 100-112, and 116-130 under 35 U.S.C. § 112, first paragraph, scope of enablement, has been withdrawn.

Applicants note with appreciation that the rejection of claims 23, 89, 102-105, 108, 111, and 118 under 35 U.S.C. § 103(a) has been withdrawn.

Applicants note with appreciation that the rejection of claims 13, 21, 87, 88, 93, 94, and 102 under 35 U.S.C. § 112, second paragraph, has been withdrawn.

2. Claim Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 21, 23, 28, 29, 50, 57-60, 76, 77, 85, 88, 89, 102-112, 116-123, and 125-129 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to enable one of skill in the art to practice the claimed invention. Applicants traverse this rejection to the extent it is maintained in light of the amended claims.

Applicants maintain the arguments of record. Applicants have presented working examples demonstrating the ability of PYY to affect glucose responsiveness, and have pointed to several places in the specification and claims as filed which provide enabling support for the use of a PYY agonist or biologically active fragment thereof to treat a disease associated with glucose metabolism. Applicants respectfully submit that the Office has failed to meet its burden to present a supporting disclosure or affidavit to back up its assertion that Applicants' invention is not enabled. The proper standard for making an enablement rejection is not whether the Examiner believes that a PYY agonist can alleviate adverse effects or symptoms of a disease associated with abnormal glucose metabolism, such as hyperlipidemia or hyperlipoproteinemia. Applicants have provided an enabling statement as well as an effective dose range, and thus

absent evidence to the contrary, the invention is enabled. Furthermore, Applicants do not understand the relevance of the Examiner's assertion that the specification "fails to teach a reduction in plasma free fatty acid (FFA) concentrations upon PYY administration (demonstrating PYY stimulates lipolysis)" (Office Action, page 4). Lipolysis is the breakdown of fats to produce FFAs.

Nevertheless, to expedite prosecution, Applicants have amended claims 21, 23, 88, 89, 102, and claims dependent thereon, to recite that "the PYY or biologically active fragment thereof binds a PYY receptor and promotes glucose responsiveness," as suggested by the Examiner. Applicants' amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope.

Additionally, Applicants provide herewith the declaration of Dr. Christine Mack under 37 C.F.R. § 1.132. The declaration of Dr. Mack provides further support for Applicants' disclosure that PYY can be used to treat diseases associated with glucose metabolism, wherein the disease comprises hyperlipidemia and/or hyperlipoproteinemia.

Dr. Mack has extensive experience as a researcher in the field of hormone research. Dr. Mack is currently a Senior Scientific Investigator in the Discovery Research Department at Amylin Pharmaceuticals, Inc., a current licensee of the instant application. Dr. Mack's own experiments have shown that bioactive fragments of PYY, specifically PYY[3-36], can lower plasma levels of total cholesterol and triglycerides in rats. In an exemplary experiment detailed in Dr. Mack's declaration, diet-induced obese (DIO) rats were treated with PYY[3-36]. Rats treated with this PYY agonist exhibited a decrease in total plasma cholesterol levels and plasma triglyceride levels in comparison to treatment with vehicle alone. Thus, by showing that PYY can be used effectively to lower plasma levels of total cholesterol and triglycerides in a DIO animal model, Dr. Mack's declaration provides further evidence consistent with the teachings of the specification that PYY may be useful in the treatment of, among other conditions, hyperlipidemia and hyperlipoproteinemia.

In light of Applicants' amendments to the claims, and in view of the declaration of Dr. Mack, Applicants contend that the pending claims are enabled throughout their scope. Reconsideration and withdrawal of the rejection are respectfully requested.

3. Claim Rejections Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 109, 112, and 119 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, claims 109, 112, and 119 are rejected because the specification allegedly fails to provide support for Applicants' previous amendments. Applicants traverse this rejection and contend that the rejection is moot in light of the amended claims.

Applicants contend that the specification provides ample support for the previously pending claims. Nevertheless, to expedite prosecution, Applicants have amended the claims to more literally parallel the language recited in the application. Applicants' amendments are not in acquiescence to the rejection. Applicants reserve the right to prosecute claims of similar or differing scope. In light of Applicants' amendments, reconsideration and withdrawal of the rejection is requested.

Applicants note with appreciation the Examiner's acknowledgement that claims 13, 15-20, 30-33, 39, 45, 46, 53, 54, 78, 87, 90-94, 96-98, 100, 101, and 130 are allowed.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945, under Order No. CIBT-P01-058.**

Respectfully Submitted,

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Melissa S. Rones
Reg. No. 54,408
Ropes & Gray LLP
One International Place
Boston, MA 02110
Phone: 617-951-7000
Fax: 617-951-7050